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The International Comparative Legal Guide to:

# Pharmaceutical Advertising 2018

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A practical cross-border insight into pharmaceutical advertising

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## General Chapter:



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## Country Question and Answer Chapters:

# Russia

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

Basic law is the Federal Law On Advertising (No. 38-FZ dated March 13, 2006) ("Law on advertising"). There are also official clarifications of competent authorities that clarify law provisions but do not alter them. Moreover, the AIPM Code of Conduct ("AIPM Code"), adopted by the Association of International Pharmaceutical Association, provides additional rules for member companies.

### 1.2 How is "advertising" defined?

Advertising is defined by the Law on advertising as: "information spread by any means, in any form and by any media, which is addressed to an indefinite circle of persons and aimed at drawing attention to advertised object, at creating or maintaining interest in it and at promoting it in the market".

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

All items must be authorised prior to advertising them in Russia. Companies must also have all data mentioned in advertising confirmed documentarily, including respective researches and testing results. All advertising materials and any related documents must be stored within one year after the last distribution of the advertisement.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no statutory requirements for companies, except for those regarding storing advertising materials.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

There is no preliminary approval procedure provided under the Russian law.

### 1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

Competent authorities are entitled to demand ceasing violations of law and distribution of illegal materials under an official decision, which may be further appealed to the court. The authorities are not entitled to insist on the issuance of a corrective statement.

### 1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

Breaching law requirements in part of pharmaceutical advertising shall cause administrative liability in the form of a fine in the amount of up to RUR 2,500 (approx. EUR 40) for individuals, in the amount up to RUR 20,000 (approx. EUR 270) on officials, and in the amount of up to RUR 500,000 (approx. EUR 6,620) on legal entities. The fine can be calculated per breach so the total amount can be above the higher level. Another risk can be blocking an information resource in Russia.

Competent authority is the Federal Antimonopoly Service of the Russian Federation ("FAS"). Within the scope of its powers the FAS initiates and holds administrative proceedings on violations of advertising requirements. According to recent practice, the authority

initiated several cases against major pharmaceutical companies, including Sanofi. The total fine under five cases initiated against Sanofi composed RUR 1,000,000 (approx. EUR 13,200).

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

There are expert committees established by the FAS in its regional departments. These are not self-regulation institutions *per se*, although they do have some influence on decisions made by the FAS and the FAS tends to rely on an opinion of the committee when assessing advertising materials in question.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

A competitor affected by the advertisement may file a claim to the FAS on unfair advertising, as well as initiate legal proceedings on the protection of business reputation, if applicable.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Discussing medicines at scientific events and meetings for healthcare professionals is not prohibited under Russian law and can be initiated before the required authorisation is obtained. However, such discussion should not pursue the aim of promotion. Sponsorship of the meetings will be in question since advertising laws will apply. Should such sponsor support the event only with the purpose to conduct discussion of its product before authorisation, such sponsorship might be considered a veiled advertisement of an unauthorised product that is prohibited under Russian law. The position will be the same for off-label information.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Publishing information about medicines with a neutral nature of content (e.g. with no aim to promote the item) is permitted, and in particular, this can be analytical and scientific materials on recent developments in a disease treatment method.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Creating publications with respect to unauthorised products is prohibited, unless such publications have no aim to promote the respective item but only to keep the public informed of scientific or medical progress. As regards press releases, they are designed primarily for promoting the subject-matter focusing on a particular item, which is similar to the advertisement concept. Therefore, there will be a high risk of recognising such press releases as unlawful advertising.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Non-promotional materials are free to circulate between healthcare professionals and companies may distribute them. It should also be also noted that healthcare professionals have a right to request such information, in which case a personalised reply to such request will not reflect advertising criteria. This will not apply to press releases due to their promotional nature, and distribution thereof is prohibited until authorisation is obtained.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The case did not have any direct influence either on legislation or on practice. However, it is likely that the same position, as provided by the ECJ, may be reflected in Russian disputes.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

In general, all prices are set when all formalities are completed and therefore any distribution of medicines or indications before obtaining authorisation will not work for procurement justification for Russian institutions. Therefore, providing such medicines or indications will hardly be treated as an attempt at planning the budgets, and will more likely be regarded as advertising.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

According to the Law on drug circulation (Federal law No. 61-FZ dated April 12, 2010) ("Law on drug circulation"), pharmaceutical

companies may engage healthcare professionals in scientific and educational works. Thus, it is possible to pay healthcare professionals for marketing research if their participation implies material contribution to studies. Such marketing studies cannot be used for the promotion or selling of any pharmaceutical products, managing the opinions of the participants of the study or pre-registration promotion for any pharmaceutical product in any instance.

## 3 Advertisements to Healthcare Professionals

### 3.1 What information must appear in advertisements directed to healthcare professionals?

There are no special requirements for this group. However, companies usually use a legal line in the marketing materials stating that the information is intended for healthcare professionals only.

### 3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

There are limited restrictions, apart from the general rules in advertising laws that prescribe specific restrictions on the content of pharmaceutical advertising. Advertising targeting healthcare professionals must not:

- refer to completed research as an advantage if such research are compulsory for the state registration of the product;
- contain the assertion or assumption that the consumers of the advertisement have certain diseases or health disorders;
- assist in causing a healthy person to gain the impression that he/she should use the product;
- create the impression that there is no need to visit a medical doctor;
- guarantee a positive effect from the product, its safety, efficiency and lack of by-effects;
- present the object of advertising as a biologically active supplement and food supplement or other products not being medicines; and
- contain the assertion that the safety and/or effectiveness of the product are guaranteed by its natural origin.

Describing properties and characteristics, including methods of application and use of medicines and medical articles, is permitted in advertisement only to the extent of indications contained in instructions ("SmPC") for application and use of such objects of advertising that are approved in the established procedure.

### 3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

Using endorsements by healthcare professionals is a limited tool for promoting medicines, which is acceptable only for advertisement disseminated during pharmaceutical events or in printed materials for healthcare professionals.

### 3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

There are no requirements to a particular number of "head to head" trials. The only requirement for comparison is that it shall be based on objective criteria.

### 3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

Comparisons between different brands are not prohibited for advertising provided that all data is correct and proved documentarily, as well as not violating intellectual property rights of the brand holder. However, referrals to non-authorised products should be avoided due to the general prohibition of their advertising.

### 3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

The Law on drug circulation mandates that participation of pharmaceutical companies, other than the organiser of the event, shall not be restricted or be of discriminatory nature. No participation fees shall be established in a manner leading to an unreasonable restriction on participation either. Information about the date, time and place of such event shall be published on the official website of the organiser no earlier than two months prior to its beginning. In addition, information on such event shall be submitted to an authorised governmental body for further official publication on its website.

### 3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

"Teaser" advertisements shall fall under general regulations prescribed for advertising in Russia as set out herein.

## 4 Gifts and Financial Incentives

### 4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

The Law on drug circulation prohibits the provision of samples of medicinal products to healthcare professionals in case the samples are provided for a subsequent transfer to patients, with the exception of the provision of samples for the conduction of clinical trials. Additionally, AIPM members are not allowed to provide healthcare professionals with any samples of pharmaceutical products for personal use.

### 4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

All gifts and donations are prohibited for pharmaceutical companies both by the Law on drug circulation and the AIPM Code. In practice, the provision of stationery of insignificant value free of charge during educational and scientific events is allowed.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

If a healthcare organisation and a pharmaceutical company are registered as commercial companies in Russia, such gifts or donations of any kind are prohibited. If a healthcare organisation is a non-commercial company, the Law on advertising prohibits the donation of samples containing narcotic substances. Thus, all other gifts and donations are allowed (a) in the absence of direct prohibition, and (b) for publicly beneficial purposes subject to the absence of conflict of interests.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

Subject to compliance with the restrictions indicated above, the provision of medical or educational goods and services to healthcare professionals which could lead to changes in prescribing patterns is allowed.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

In general, Russian legislation does not prohibit the provision of a volume-related discount for the purchase of medicinal products by healthcare institutions. However, a respective discount should be commercially reasonable, otherwise it may trigger tax or anti-monopoly/anti-bribery restrictions.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

It depends on whether such offer is reflected in agreement between the pharmaceutical company and medical institution or respective services are provided unofficially to the executive officer of a medical institution in exchange for the purchase of a medicinal product. While Russian legislation does not prohibit the former, the latter is likely to be regarded as a bribe. Thus, in order to comply with Russian laws, the respective offer should be included in the agreement between a pharmaceutical company and medical institution for the purchase of medicinal products.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

References to refunding can be regarded as unlawful assurance of the effectiveness and safety of a product that is prohibited from the advertising law perspective, and this will be equally relevant to any types of medicines.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Pharmaceutical companies are allowed to sponsor the scientific activities of healthcare professionals, which may include medical education.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Russian legislation does not establish special anti-bribery rules applying to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations. According to the Criminal Code of Russia, the following actions are forbidden:

- the provision of money or other property as well as services or rights to the executive official of the company for certain actions or omission to act in the interests of a person or entity providing money, securities, etc. in case (i) the relevant actions are not based on law or agreement, and (ii) these actions or omission to act are included in his duties as the official of the company (as well as the provision of these items to the third party at the instruction of such executive official);
- receipt of money, securities and other property as well as services or property rights by executive official as described above; and
- actual transfer of money, securities, other property or property rights, as well as the provision of services in the situations described above at the order of the person providing items listed above, or any other assistance to these persons.

According to practice, Russian authorities can exchange information transferring matters to the relevant state body for its consideration. However, due to the limited scope of anti-bribery legislation, a situation where a pharmaceutical company may breach both advertising and anti-bribery laws simultaneously is unlikely.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

According to Russian legislation, it is prohibited for pharmaceutical companies to pay healthcare professionals for entertainment, leisure and travel costs, as well as engage them in entertainment events conducted at the expense of such pharmaceutical companies with the exception of scientific meetings.

Respective prohibition applies regardless of the place where such events take place and the cost of them. However, the AIPM Code states that pharmaceutical companies should not organise events for healthcare professionals outside their country of residence, unless it is justified in terms of logistics or security. The use of facilities associated with entertainment or luxury is prohibited.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

Though the Russian legislation does not directly restrict the pharmaceutical company from paying healthcare professionals attending the scientific meeting, respective expenses are hard to justify in the absence of any benefit (such as internal education courses or follow-up lectures for the employees) for the company from their participation. Therefore, this option is not advisable.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

The pharmaceutical company may be held liable for the breach of advertising legislation at these meetings in case it either organised such meeting or sponsored it in such a way that allowed such pharmaceutical company to include the breach of advertising in the context of a meeting. There is no direct liability prescribed for hospitality arrangements, although this might trigger associated liability (tax, anti-bribery, antitrust etc.). The compliance of Russian pharmaceutical companies with these requirements is mostly dependent on them acting in good faith.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Pharmaceutical companies may pay healthcare professionals (except for pharmaceutical professionals and heads of pharmacy organisations) serving as experts for their work on the expert council, provided that the experts' work on the expert council is scientific in nature. However, the requirements stated in question 5.2 should be observed.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

The participation of healthcare professionals in clinical studies is allowed. Respective clinical studies should be done according to applicable legislation.

Please note that the participation of a healthcare professional should be structured in such a way that it does not lead to a conflict of interest.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

According to the Law on drug circulation, a pharmaceutical company can pay a healthcare professional in connection with scientific and educational work. Thus, we believe it is possible to pay healthcare professionals for marketing research in case their participation implies material scientific work done by such healthcare professionals.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Non-prescription medicines are permitted to be advertised to the general public. The basic requirement is that the advertisements should be fair and true.

The following actions are generally prohibited:

- advertising certain objects and products (e.g., human organs and tissues for sales purposes; those manufactured with the use of human embryo tissues);
- advertising of narcotic or psychotropic substances and their precursors;
- advertising of non-authorised items;
- advertising of prescription medicines, treatment methods, medical products and equipment that require special training for their use to general public; and
- depicting healthcare professionals.

According to additional rules, advertising of non-prescription medicines must not:

- be addressed to minors;
- contain references to specific cases of recovery from disease or improvement of health as a result of using an advertised item;
- contain expressions of gratitude from individuals in connection with the use of the advertised item;
- create an impression of the advantages of the advertised item by reference to the fact that the trials required for its state registration have been conducted;
- contain statements or assumptions that consumers have certain diseases or impairments of health;
- facilitate the impression that a healthy person needs to use the advertised item (this prohibition does not apply to medicines used for the prevention of diseases);

- create an impression that one does not need to consult a physician;
- guarantee the positive effect of the product, its safety, effectiveness and absence of side effects;
- represent the advertised object as being a dietary supplement (or bio-active supplement) or other product that is not a medicine; and
- contain statements that the safety and/or effectiveness of the advertised item are guaranteed by its natural origin.

Very important to note, is that the advertising of medicines, medical services and equipment must be accompanied by a warning regarding contraindications against their use and application, and the necessity to read the instructions on their use or the necessity to consult a specialist.

All information placed in advertising materials must correspond to SmPC.

Medicines containing permitted narcotic or psychotropic substances are prohibited for advertising to the general public.

Russia has also set forth a specific regulation for biologically active additives.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

Advertising prescription-only medicines, treatment methods, medical products and equipment requiring special training for their use is prohibited to the general public.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

If conducted campaigns do not include any product names, they will not draw attention to any items and thus advertising regulations will not apply. However, according to advertising laws, specific restrictions set for promoting certain products will apply to the promotion of any names, brands and other means of individualisation associated with such products. Therefore, running any campaigns by manufacturers or sellers specialised on prescription-only medicines can be recognised as veiled advertising of prescription-only medicines even in silence of particular product. If so, restrictions prescribed for prescription-only medicines will apply.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Referring to prescription-only medicines is prohibited in publications made in printed materials if they are available to the general public, unless they are of a purely informative nature and only have the aim to keep the public informed about scientific or medical progress. Information and analytical materials (scientific research and testing results) are excluded explicitly from advertising regulation. However, press releases are closer to advertisement concept, since they are focused on a particular item. Therefore, general and specific requirements provided for prescription-only medicines might apply. Similarly to the aforementioned, unauthorised medicines or indications is only permitted for informative purposes.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

It is a general requirement that information must be true and accurate. According to Russian law, information about prescription-only medicines is allowed for distribution only through sources intended for healthcare professionals; only information about non-prescription medicines is permitted for dissemination to the general public. Therefore, providing a description of prescription-only medicines exceeding the name of the product might be an issue.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

There is no official regulation in Russia and therefore general advertising rules will apply to this group, if their communication is related to promoting medicines. Any meetings with, and the funding of such organisations are allowed, provided that they comply with the law. In case funding is part of the sponsorship campaign it will be recognised as advertising, and thus only permitted with respect to non-prescription medicines.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Russian law provides for a specific prohibition in distributing samples of medicines containing narcotic or psychotropic substances. Providing samples of prescription-only medicines is also restricted since it may be deemed advertising.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

The Rules of Good Clinical Practice approved by the Ministry of Health provide detailed instruction regarding the exchange of information between the participants of clinical trials such as medical organisation, patients, state bodies, etc. However, it is not necessary for information on clinical trials to be disclosed to the public.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

The Russian legislation does not provide for such requirement.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Respective requirements are reflected in the AIPM Code. It is applicable to all companies, which voluntarily endeavour to comply with the AIPM Code.

Each pharmaceutical company shall document and disclose the following transfers of value it makes, directly or indirectly, to or for the benefit of any healthcare professional or healthcare organisation being a recipient:

- donations and grants;
- contribution to costs related to events; and
- fees for service and consultancy.

Without limitation, transfers of value that: (i) are solely related to over-the-counter pharmaceutical products; (ii) are not listed above and are not restricted by applicable legislation and the AIPM Code; or (iii) are part of ordinary course purchases and sales of pharmaceutical products do not fall within the scope of the disclosure obligation.

Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year. Disclosures shall be made by each pharmaceutical company within six months after the end of the relevant reporting period and the information disclosed shall be required to remain in the public domain for a minimum of three years after the time such information is first disclosed, with some exceptions.

Disclosures are made on the relevant pharmaceutical company's website, provided that it is publicly available.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

The AIPM Code does not directly regulate such situation. Since the respective transfers of value can be disclosed in a summarised and depersonalised way, we believe that the transfers of value to such individual healthcare professional may be disclosed by the company in a depersonalised way.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Russian law does not provide for specific regulation of digital pharmaceutical advertising. Therefore, the same requirements will apply to such information source as if respective materials were distributed in other forms.

It is allowed to have information resources for the purposes of providing information about a company or/and its products, etc. Consequently, it is allowed, *inter alia*, to display the name of the product, although this should not imply promoting purposes. Should this criteria be met, the information resource will not be subject to advertising regulation. Otherwise, all promoting materials placed on the Internet must comply with the general requirements set by advertising laws.

Russian laws are in the process of elaborating their approach to determining the jurisdiction of information sources. Currently, Russian authorities that are entitled to monitor websites have their own ways to determine jurisdiction. In terms of advertising regulations, the official regulator monitors websites hosted on national domains (e.g., .ru, .рф, .su, etc.) as well as foreign websites with webpages in the Russian language.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

Pursuant to Russian law, restricting access is required with respect to information related to prescription-only medicines. The law does not clarify the rules on adequate and sufficient measures to be undertaken in order to restrict access to sites for healthcare professionals. In practice, pharmaceutical companies disseminate information on prescription-only medicines via specialised social media, where a user must pass a verification procedure to have access. However, the law and current regulation are silent on legitimacy in this way.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

Russian rules do not address weblinks *per se*. Authorities consider this issue on a case-by-case basis. The current approach is that companies are not restricted in using weblinks to or from independent websites. References to websites for healthcare professionals would not generally be acceptable on websites designed for the public, since such healthcare professionals sites might contain restricted advertising. The law is also unclear on how to allocate liability when a weblink leads to an independent website with unlawful content. According to current practice, a company will likely be held liable if it has any relationship with both the linked-from and linked-to websites. Otherwise, it shall only be responsible for the content on its own website. Nevertheless, the safe option is to monitor independent websites for compliance with the applicable law.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

General corporate websites are acceptable in Russia so long as they do not promote prescription-only medicines or unauthorised products to the public. General information about medicinal products (e.g. names) on websites falls outside the scope of advertising rules unless it is arranged in a manner to make any one stand out from others.

It is permitted to distribute advertising of non-prescription medicines through the website subject to compliance with applicable requirements as provided herein.

### 8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

Russian laws do not provide for specific regulation with respect to social media. Therefore, the same requirements will apply to a page on a social network.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

No significant changes in pharmaceutical advertising regulation have been made over the last year.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

Currently, one of the most debated topics is using the words "fast", "effective" in advertising of medicines. There are numerous cases when the authorities deemed advertisement containing such words as guaranteeing a positive effect, which is prohibited under the laws. It is expected that during 2018 there will be a guideline adopted on the acceptability of using such words in advertising.

It has also been proposed to restrict TV advertising of medicines, and the respective bill is under consideration currently.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

According to recent cases, authorities tend to focus on the description of the effect of a particular medicine provided by an advertiser. It appears from the practice that any statements promising an immediate or quick recovery are not acceptable.

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Maria graduated from the Moscow State University in 2004 and was awarded an LL.M. degree in private law by the Russian Private Law School by the President of the RF in 2006. Maria joined ALRUD team the same year. She became a Partner in 2016. She is a member of the International Bar Association and International Association of Privacy Professionals.

ALRUD

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